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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,952	06/23/2003	Karl A. Jagger	29985/03-057	7910

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EXAMINER	
SONNETT, KATHLEEN C	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/601,952	JAGGER ET AL.	
	Examiner	Art Unit	
	Kathleen Sonnett	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *1-8 and 21-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-20* is/are rejected.

7)☒ Claim(s) *12* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 June 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/29/03,3/19/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: *IDS: 9/30/04,2/16/06*.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II, Species B in the reply filed on 7/10/2006 is acknowledged. The traversal is on the ground(s) that a restriction between types of crimping elements and a stepped enclosure is improper because independent claim 9 requires both elements. The examiner would like to reiterate that the election of species is directed at the *stepped tube,* not the stepped enclosure. The argument of applicant is not found persuasive because as disclosed in the specification, page 9 lines 32+, "the crimping device (50) may be employed which would eliminate the need for the stepped *tube*" and thus the crimping device and stepped tube are used in two different embodiments of the invention. Furthermore, the stepped enclosure takes the form of a stepped tube in claim 13 and a plurality of crimping elements in claim 14. The recitation of both the step of crimping and placing a stepped enclosure over the stent does not affect an election of species as the recitation of two species within one claim is not relevant. Therefore, the election of species is deemed proper. However, the examiner agrees that applicant's election of species B, the crimping elements, reads on all of Group II, claims 9-20 since the inside edges of the crimping elements form a stepped enclosure that can be considered a stepped tube.

The requirement is still deemed proper and is therefore made FINAL.

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the temperature range for the heating medium supplied during balloon inflation is given as about 40°C to about 85°C on page 8, line 26 of the instant specification but

is claimed in claims 18 and 20 as "about 40 to about 60°C". For the following claim rejections, the examiner has treated the claims as though they read from about 40°C to about 85°C as disclosed in the specification.

Claim Objections

3. **Claim 12** is objected to because of the following informalities: typographical error in line 2 of claim 12 reading "a flared proximal distal end" with regards to the first section of the stepped tube. It appears to the examiner, based on page 9, lines 17-18, the claim should read "a flared proximal end" with respect to the first section of the stepped tube, the first section being the proximal and/or larger diameter section of the tube. Additionally, based on the specification, it appears that the second section of the stepped tube comprises a flared *distal* end, whereas the claim reads "the second section of the stepped tube comprises a flared proximal end".

Appropriate correction is required

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 12 recites the limitation "the stepped tube" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 9, 13, and 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Jendersee et al. (U.S. 5,836,965). Jendersee et al. discloses a method for fabricating a balloon catheter stent deployment system comprising:

- providing a balloon catheter with an inner tubular shaft disposed within an outer tubular shaft, the inner and outer shafts each having proximal and distal ends, the distal end of the inner shaft (40) extending distally beyond the distal end of the outer shaft (30), and an inflatable balloon (inflatable portion of 30, "36") having a proximal end attached to the outer shaft near the distal end thereof and a distal end attached to the inner shaft near the distal end thereof (col. 5 lines 24-30)

- placing a stent (10) over the balloon so that a distal end of the stent is disposed proximally to the distal end of the balloon and a proximal end of the stent is spaced distally from the proximal end of the balloon leaving a proximal section of the balloon uncovered by the stent that extends from the proximal end of the stent to the proximal end of the balloon (Fig. 3) (see col. 6, lines 52-57; fig. 3; and col 3 lines 54-57 with regards to the distal end,

- crimping the stent onto the balloon to leave the stent with initial outer diameter (col. 6 lines 42-45)

- placing a stepped enclosure over the stent and balloon wherein the stepped enclosure comprising a first section having a first inner diameter and that is connected to a second section having a second inner diameter, the first inner diameter being greater than or equal to the

second inner diameter, the second inner diameter being greater than the initial outer diameter of the stent but in close approximation thereto, the second section of the stepped enclosure being at least as long as the stent, and wherein the first section of the stepped enclosure is disposed over the proximal section of the balloon and the second section of the stepped enclosure is disposed over the stent, (see col. 6, lines 52-57; fig. 3; and col 3 lines 54-57)

- inflating the balloon so that the proximal section of the balloon inflates and engages the first section of the stepped enclosure and the stent and balloon disposed beneath the stent and distally of the stent are prevented from substantial expansion by the second section of the stepped enclosure, enclosure (see col. 3 lines 54-57 with regards to the balloon section that is distal of the stent being prevented from substantial expansion)

- removing the balloon and stent from the stepped enclosure (col. 7 lines 25-26)

9. Regarding claim 13, the stepped enclosure is a stepped tube and the second section (42) of the stepped tube extends into the first section (44) of the stepped tube to provide an overlap section between the first and second sections (see fig. 3).

10. Regarding claims 16 and 17, Jendersee et al. discloses applying heat to the balloon during crimping (i.e. encapsulation) in a temperature range from about 50° to about 85°, particularly about 65° (150° F = 65.6° C; col. 6 lines 58-67).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jendersee et al. in view of Miraki et al. (U.S. 5,704,845). Jendersee et al. discloses the invention substantially as stated above, but fails to disclose inserting a protective sleeve over the stent after removing the balloon from the stepped enclosure.

13. However, Miraki et al. discloses that it is old and well known to house a balloon catheter in a protective sleeve (52) before use in order to keep the catheter sterile (col. 3 ll. 19-21). This protective sleeve is put on the finished catheter and is therefore placed over the catheter after the manufacturing process. Therefore, it would have been obvious to one of ordinary skill in the art to modify the method of Jendersee et al. to include inserting a protective sleeve over the stent as made obvious by Miraki et al. in order to keep the stent sterile. Miraki et al. does not disclose keeping the protective sleeve in a position proximal to the balloon prior to and during a manufacturing step and then sliding it over the balloon after the step is completed. However, applicant has not disclosed that keeping the sleeve premounted on the catheter proximal to the stent and then sliding the sleeve over the stent after removing the stepped tube is used for any particular purpose, or provides any advantage. Furthermore one of ordinary skill in the art would expect the modified method of Jendersee et al. and applicant's claimed method to perform equally well using either a protective sleeve that is premounted proximally of the stent and then slid over the stent or a protective sleeve that is slide over the stent from the distal end of the stent.

14. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jendersee et al. in view of Euteneuer et al. (U.S. 5,147,302). Jendersee et al. discloses the method substantially as stated above but fails to disclose flared ends on the stepped tube.

15. However, Euteneuer et al. discloses that it is old and well known in the art to include flared ends on tubes (50) that are placed over a balloon in order to reduce abruptness of the

leading edge of the tube (col. 4 ll. 7-15). Reduced abruptness allows for easier placement of the tube over the balloon. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Jendersee et al. to include flared ends on the stepped tube in order to facilitate placement of the stepped tube over the stent and balloon as made obvious by Euteneuer et al.

16. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jendersee et al. in view of Motsenbocker et al. (U.S. 6,629,350). Jendersee et al. discloses the invention substantially as stated above, but fails to disclose the stepped enclosure (mold) being formed by a plurality of crimping elements each having a stepped leading edge to form the stepped enclosure that are capable of heating the stent and the balloon.

17. However, Motsenbocker et al. discloses that it is old and well known in the art to use a plurality of crimping elements, each having a stepped leading edge (col. 7 ll. 55-59), to form a stepped enclosure wherein the crimping elements are movable between crimping and retracted positions (see abstract). Motsenbocker et al. discloses that this device is superior to stepped tubes because the bore size of a stepped tube limits the diameter of the stent (col. 1 ll. 47 and 63+), which is avoided using the crimping elements. Furthermore, Motsenbocker et al. discloses that heaters may be placed in the crimping elements (col. 13, ll. 7-10) so that heat may be applied during crimping as is well known in the art. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Jendersee et al. to include a plurality of crimping elements with stepped edges that are capable of delivering heat as made obvious by Motsenbocker et al. to form the stepped enclosure (mold) in order to gain the advantage of a changing bore size to facilitate insertion of the stent and balloon catheter into the mold.

18. Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jendersee et al. Jendersee et al. discloses the method as stated above and further discloses pressurizing the balloon to an internal pressure ranging from about 30 to about 75psi (col. 6, line 64). Jendersee et al. fails to discloses a time period for pressurizing the balloon ranging from 5 seconds to about 1 minute. However, applicant has not disclosed that pressurizing the balloon for a period ranging from 5 seconds to about 1 minute solves any stated problem, is used for any particular purpose, or provides any advantage. Moreover, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (*In re Aller,* 105 USPQ 233).

19. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Jendersee et al. such that the time period for pressurizing the balloon ranges from 5 seconds to about 1 minute because such a modification would have been considered a mere design consideration which fails to patentably distinguish over Jendersee et al.

20. Regarding claims 18 and 19, Jendersee et al. includes the step of inflating the balloon with gas but is silent on the temperature of the gas. However, applicant has not disclosed that the temperature of the gas in the range from about 40° to about 60° C (in spec. 40° to 85° C) is used for a particular purpose or provides any advantage. Furthermore, applicant discloses in the instant specification that the gas may alternatively be delivered at ambient temperature with no disadvantage disclosed (p. 8 ll. 23-26). One of ordinary skill in the art would expect the method of Jendersee et al. using an ambient temperature to perform equally as well as applicant's claimed temperature range (40 to 60°C) since no disadvantage is disclosed for using ambient temperature gas for inflation. Moreover, Jendersee et al. exposes the inflated balloon to a temperature of 65° C after inflation to help set the stent, and therefore the gas will reach this

temperature. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Jendersee et al. to include the step of delivering gas having a temperature range from about 40° to about 60° C because such a modification would have been considered a mere design consideration which fails to patentably distinguish over Jendersee et al.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

U.S. 6,948,223 to Shortt

U.S. 6,561,788 to Gaudoin.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS
8/10/2006

GLENN K. DAWSON
PRIMARY EXAMINER